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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
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09/292,723 04/15/99 READHEAD

C P0741795

EXAMINER

HM22/1004

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LOS ANGELES CA 90071-2909

MARTIN, J

ART UNIT

PAPER NUMBER

1632

DATE MAILED:

10/04/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

FILE

Office Action Summary

Application No.
09/292,723

Applicant(s)

Readhead et al.

Examiner

Jill D. Martin

Group Art Unit

1632



☐ Responsive to communication(s) filed on _____

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 1 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claims

☒ Claim(s) 1-132 is/are pending in the application.

Of the above, claim(s) _____ is/are withdrawn from consideration.

☐ Claim(s) _____ is/are allowed.

☐ Claim(s) _____ is/are rejected.

☐ Claim(s) _____ is/are objected to.

☒ Claims 1-132 are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☐ None of the CERTIFIED copies of the priority documents have been

☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☐ Notice of References Cited, PTO-892

☐ Information Disclosure Statement(s), PTO-1449, Paper No(s). _____

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Election/Restriction

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-62, 75-82, 94-101, and 107-117, drawn to methods of transferring nucleic acid into the gonad of a vertebrate to make selectable transgenic stem cells, the transgenic vertebrates, transgenic selectable germ cells, and method of making the said vertebrates by breeding, classified in class 800, subclass 13, for instance.
- III. Claims 63-74, and 83-93, drawn to a method of transferring nucleic acids into germ cells, *in vitro*, classified in class 435, subclass 440, for instance.
- III. Claims 102-106, and 118-132, drawn to nucleic acid constructs comprising cyclin A1 promoter, and further in operable linkage with a marker gene, and kits comprising a transfection agent and the same nucleic acid constructs, classified in class 435, subclass 320.1, for instance.

The inventions are distinct, each from the other because of the following reasons:

Inventions I and II are distinct because they are materially different processes, each resulting in transfer of nucleic acids into a germ cell. However, the processes are distinct because each has unique steps and either can be made and used without the other. For instance, the invention of group III recites a method of transferring a nucleic acid into a germ cell *in vitro*. This method can be for the purpose of producing a protein, for example. The method of group I is specifically directed to transfer of a nucleic acid to the gonad of a vertebrate for a specific purpose, i.e., production of transgenic vertebrate so that the germ cells of said gonad are then

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selectable. As such, the method of group I can be carried out without the method of group II, and *vice versa*.

Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product of group I can be used in materially different processes such as that recited in either of groups I or II and also to transfect any other cell.

Inventions I and III are directed to distinct products. Though the product of group III could be used in the making of the product of group I, the product of group III can be used in materially different processes such as transfecting cells for the purpose of producing a protein.

Because these inventions are distinct for the reasons given above, have acquired a separate status in the art as shown by their different classification, and require different searches, restriction for examination purposes as indicated is proper.

This application contains claims directed to the following patentably distinct species of the claimed invention: where the vertebrate is a mammal or bird or where the source of polynucleotide is from a mammal or bird.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held

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to be allowable. Currently, claims 1-8, 11-29, 32-49, 52-70, 73-89, 92-115, and 118-132 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently

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named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jill Martin whose telephone number is (703)305-2147.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Karen Hauda, can be reached at (703)305-6608.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703)308-0196.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.



Jill D. Martin
Patent Examiner
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